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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,162	06/25/2003	Jose Remacle	KLAUS2.002AUS	3585

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Knobbe Martens Olson & Bear LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

EXAMINER

Petersen, Clark D

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,162	Applicant(s) REMACLE ET AL.	
	Examiner Clark D. Petersen	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-29, drawn to a method of determining the activation state of a cell by determining the equilibrium between its kinase and phosphatase activities, using capture molecules on a solid support to stabilize and characterize kinase/phosphatase target proteins, classified in class 435, subclass 7.1, for example.
- II. Claims 30-32, drawn to a kit for evaluation of an activation level of a cell by quantification of a level of phosphorylation of multiple specific cellular proteins, a kit which includes solutions with detection molecules and a support with capture molecules, classified in class 436, subclass 63, for example.
- III. Claims 33-36, drawn to drawn to a support comprising at least five of a group of named capture molecules, classified in class 435, subclass 287.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that the process as claimed can be practiced by another materially different apparatus or by hand (MPEP § 806.05(e)). In the case of the process of characterizing cell activation through determination of the balance of

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kinase/phosphatase activity, neither the kit nor the support are absolutely necessary to achieve the process described. For example kinase assays and western blots can also convey information about a cell's activation state.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the kit of invention II, which in this case represents the combination, does not claim the requirements of the support of invention III. Invention III names specific groups of proteins that must be attached to the support for its claimed function; these particulars are not recited in the claims drawn to the kit. Additionally, the support of invention III, in this case identified as the subcombination, has separate utility such as capturing molecules of predetermined phosphorylation state, lending it separate utility as a platform for testing binding affinity or enzymatic activity of captured molecules.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. Additionally, the searches required for Inventions I, II and III are different in scope. For example, the search for Invention I (the method of claims 1-29) would require a search encompassing methods for determination of differences in cell activation that rely on data regarding cell phosphorylation state. The search required for Invention II (the kit of claims 30-32)

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would require a search of tools useful for determination of phosphorylation status of proteins. The support of Invention III (claims 33-36) would require a search for structures for immobilization of cellular proteins. Therefore, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention I, a method of determining the activation state of a cell by determining the equilibrium between its kinase and phosphatase activities (claims 1-29).

If applicant elects Invention I for further examination, he or she is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claim 1 is generic to the depending claims 15-21, which disclose a plurality of patentably distinct species comprising serine/threonine kinases (Table 1 of the specification), tyrosine kinases (Table 2 of the specification), and transcription factors (Table 3 of the specification) used in the claimed methods. Applicant must elect a single combination of proteins that may consist of at least three candidates from Table 1, at least three candidates from Table 2, at least three candidates from Table 3 of the specification, **OR** at least three candidates from the list Cyclin A, Cyclin B, Cyclin D1, Cyclin D3, Cyclin E, CDK1, CDK2, CDK4, CDK6, E2F, CDC2, cdc25c, Cdc25A, Chk2, Chk1, pRb, p53, p21, p27, and Wee1, **OR a specific combination of any of the above alternatives**, for further examination on the merits.

Additionally, claim 1 is generic to a plurality of disclosed patentably distinct species listed in claim 27, wherein are listed types of treatment that could affect a cell's activation state, namely physical, chemical, physiological treatment, or drug administration. Applicant is required to select one type of treatment for further examination.

If applicant elects Invention III (claims 33-36) for further examination, he or she is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic to the depending claims 34-36, which disclose a plurality of patentably distinct species comprising serine/threonine kinases (Table 1 of the specification), tyrosine kinases (Table 2 of the specification), and transcription factors (Table 3 of the specification). Applicant is asked to elect a single combination of at least five candidate proteins from Table 1 of the specification (per claim 33), a single combination of at least five candidate proteins from Table 2 of the specification (per claim 34), five candidates from Table 3 of the specification (per claim 35), **OR** a single combination of at least five candidate proteins from the list Cyclin A, Cyclin B, Cyclin D1, Cyclin D3, Cyclin E, CDK1, CDK2, CDK4, CDK6, E2F, CDC2, cdc25c, Cdc25A, Chk2, Chk1, pRb, p53, p21, p27, and Wee1 (per claim 36), **OR a specific combination of any of the above alternatives**, for further examination on the merits.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Marina Gordey on 1/25/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDP
3/17/2006


TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER